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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,045	02/17/2004	Lev Korzinov	16491-029001	8396

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EXAMINER

ROSENZWEIG, JASON

ART UNIT PAPER NUMBER

3762

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/781,045

Applicant(s)

KORZINOV ET AL.

Examiner

Jason E. Rosenzweig

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☒ Claim(s) 29-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 29, 30, and 31 are objected to because of the following informalities:
Claims state that they are dependent upon claim 23; it is assumed that claims 29,30 and 31 are dependent upon claim 28. Claims have been examined as if they were dependent upon claim 28. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 9,18, 27, 29 and 33 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.
4. Claims 9, 18, 27, and 29 disclose the use of signal morphology analysis, utilizing a signal morphology analyzer (Pg. 7 Immediately after "A possibly abnormal T wave can be determined using a") is not adequate information for someone of ordinary skill in the art to develop a device as claimed. A further search on signal morphology analyzer yielded no devices or products, which could be used in the claimed invention.
5. Claim 33 discloses a means for alerting a system operator of a possible abnormal T wave. The specification does not mention a specific means for alerting a

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system operator of a abnormal T wave, the specification only mentions that it is up to the end user to determine that a T wave is abnormal and to selectively enable a T wave filter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 11, 20, 28, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Cole (US 4887609) et al.

8. Regarding claim 1, Cole discloses: A machine-implemented method comprising: identifying heart beats in a sensed cardiac signal using a QRS detector (Fig 5, Element 22); activating a variable filter which is capable of filtering a T wave, used in said identifying heart beats, in response to a message from a monitoring station generated at least in part based upon discovery of a predetermined characteristic in the sensed cardiac signal (Col 2, Ln 21); and outputting information corresponding to the identified heart beats to a communications channel of a distributed cardiac activity monitoring system (Fig 6, Element 5C).

9. Regarding claim 2, Cole discloses: The method of claim 1, wherein said identifying heart beats comprises identifying R waves in the sensed cardiac signal (Col. 4, Ln. 5).

10. Regarding claim 3, Cole discloses: The method of claim 1, further comprising sending at least a portion of the sensed cardiac signal to the monitoring station , and wherein the discovery of the predetermined characteristic comprises identification of a tall T wave in the at least a portion of the sensed cardiac signal by an operator at the monitoring station (Fig 2, Element 5). Any ECG monitor could be used by an operator in the discovery of the predetermined characteristic, which comprises of the identification of a tall T wave in a portion of a sensed cardiac signal.

11. Regarding claim 4, Cole discloses: The method of claim 1, wherein said activating the T wave filter comprises activating a filter that reduces signal amplitude at low frequencies of the sensed cardiac signal (Col 4, Ln 28). It is noted that any filter, which has a cut off frequency within the range the low frequencies of the sensed cardiac signal, would be capable of reducing the sensed cardiac signal.

12. Regarding claim 11, Cole discloses: A distributed cardiac activity monitoring system comprising: a monitoring apparatus (Fig 5, Element 5B) including a communications interface (Fig 5, Element 4B), a real-time QRS detector (Fig 5, Element 22), a variable filter which could function as a T wave filter (Fig. 5, Element 2B), and a selector that activates the T wave filter with respect to the real-time QRS detector in response to a message (Col 2, Ln 21), wherein the activated T waver filter preprocesses a cardiac signal provided to the real-time QRS detector; and a monitoring

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station that communicatively couples with the monitoring apparatus via the communications interface and transmits the message to the monitoring apparatus (Fig 6, Element 5C) to activate the T wave filter based at least in part upon a predetermined criteria.

13. Regarding claim 20, Cole discloses: A cardiac monitoring apparatus comprising: a communications interface (Fig 6, Element 4C); a real-time heart beat detector (Fig 5, Element 22); a variable filter which can filter T waves (Fig 5, Element 2B); and a selector that activates the T wave filter with respect to the real-time heart beat detector in response to a message (Col 4, Ln. 62), wherein the activated T waver filter preprocesses a cardiac signal provided to the real-time heart beat detector (Figure 5).

14. Regarding claim 28, Cole discloses: A method comprising: receiving at least a portion of a sensed cardiac signal from a monitoring apparatus (Fig 5, Element 1B) in contact with a living being under active cardiac monitoring; wherein the device could be used by a user to identify an abnormal T wave in the received cardiac signal; and sending a message to the monitoring apparatus over a communications channel (Figure 5, Element 3B), the message causing the monitoring apparatus to activate a filter which could be used as a T wave filter in identifying heart beats of the living being under active cardiac monitoring.

15. Regarding claim 32, Cole discloses: A system comprising: means for identifying heart beats in a sensed cardiac signal (Fig 5, Element 22); means for filtering the sensed cardiac signal to reduce T waves in the sensed cardiac signal (Fig 5, Element

2B); and means for selectively activating the means for filtering in response to discovery of a predetermined characteristic in the sensed cardiac signal (Col 2, Ln 21).

16. Regarding claim 34, Cole discloses a means for filtering comprises means for generally high pass filtering (Fig 5, Element 2B).

17. Claims 1,3,4, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt (US 6167258) et al.

18. Regarding claim 1, Schmidt discloses: A machine-implemented method comprising: identifying heart beats in a sensed cardiac signal (Col 2, Ln. 8); activating a variable filter which is capable of filtering a T wave, used in said identifying heart beats, in response to a message from a monitoring station (Fig 1, Element 60) generated at least in part based upon discovery of a predetermined characteristic in the sensed cardiac signal (Col 2, Ln 50); and outputting information corresponding to the identified heart beats to a communications channel of a distributed cardiac activity monitoring system (Col 8, Ln. 19).

19. Regarding claim 3, Schmidt discloses: The method of claim 1, further comprising sending at least a portion of the sensed cardiac signal to the monitoring station, and wherein the discovery of the predetermined characteristic comprises identification of a tall T wave in the at least a portion of the sensed cardiac signal by an operator at the monitoring station (Fig 1, Element 60). Any ECG monitor could be used by an operator in the discovery of the predetermined characteristic, which comprises of the identification of a tall T wave in a portion of a sensed cardiac signal.

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20. Regarding claim 4, Schmidt discloses: The method of claim 1, wherein said activating the T wave filter comprises activating a filter that can reduces signal amplitude at low frequencies of the sensed cardiac signal (Col 10, Ln 44). It is noted that any filter, which has a cut off frequency within the range the low frequencies of the sensed cardiac signal, would be capable of reducing the sensed cardiac signal.

21. Regarding claim 8, Schmidt discloses: The method of claim 1, wherein said outputting information comprises outputting heart rate data to a wireless communications channel (Col. 3, Ln. 33).

22. Regarding claim 10, Schmidt discloses: The method of claim 1, further comprising bypassing the T wave filter in response to a Second message or signal sent to a signal selector switch when using a AD7714 (Col 11, Ln 63).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt in view of Cole.

26. Regarding claim 2, Schmidt discloses a device which collects EKG data, Schmidt does not specifically disclose the use of R waves to identify beats in a cardiac signal however Cole explains that it is common in the art of identifying heart beats from a EKG signal to use the R wave (Col 4, Ln. 2). It is inherent to use the R wave as a predetermined identifier because of it's usually high peak compared to the rest of the EKG signal. Therefore it would be obvious to one of ordinary skill in the art to use a QRS detector which tracks the R waves in a sensed cardiac signal in a device which records EKG data (Col. 4, Ln. 17).

27. Claim 12,13, 17, 21, 22, 23, and 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cole in view of Schmidt.

28. Regarding claim 12, 13, 17, 21, 22, 23, and 30 Cole discloses: A distributed cardiac activity monitoring system comprising: a monitoring apparatus (Fig 5, Element 5B) including a communications interface (Fig 5, Element 4B), a real-time QRS detector (Fig 5, Element 22), a variable filter which could function as a T wave filter (Fig. 5, Element 2B) by reducing signal amplitudes at low frequencies (Col 4, Ln. 57), and a selector that activates the T wave filter with respect to the real-time QRS detector in response to a message (Col 2, Ln 21), wherein the activated T waver filter preprocesses a cardiac signal provided to the real-time QRS detector; and a monitoring station that communicatively couples with the monitoring apparatus via the

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communications interface and transmits the message to the monitoring apparatus (Fig 6, Element 5C) to activate the T wave filter based at least in part upon a predetermined criteria. Cole however does not disclose the use of an interface comprising of a wireless communications interface.

Schmidt discloses: A programmable wireless data acquisition system which can be used in order to collect ECG data and also discloses the use of a AD7714 which can selectively pre-filter a measured signal allowing T-Waves to be selectively filtered before a means of identifying heart beats in a sensed cardiac signal. Schmidt does not specifically state the use of a QRS detector in his device and method. Both Cole and Schmidt disclose the use of digital circuitry in their circuits, the examiner takes official notice that a "analog, selective circuitry" could be nothing more than a analog or digital switch and in the field of electronics digital circuitry is continually replacing it's analog counterparts do to many inherent benefits mainly cost, power consumption and reliability. It would be obvious for one of ordinary skill in the art to modify Cole's device in order to have the advantage of a wireless monitoring apparatus as taught by Schmidt to remove the burden of having wires hanging off a patient especially if some sort of physical activity is required during the measuring of cardiac activity of a patient.

29. Claims 5,6,7,14,16,24,25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole.

30. The Cole reference disclose the claimed invention except for it does not specify the specified frequency response values claimed in claims 5,6,7,14,16,24 and 25. It would have been obvious to one having ordinary skill in the art at the time the invention

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was made to analyze a T wave waveform and choose cut off frequencies which could lower the amplitude of T-waves using either a digital or analog filtering method which could be done using conventional filtering techniques, Since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

31. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cole.

32. Regarding claim 31, Cole discloses the claimed invention except for he does not specify further comprising installing a T wave filter into an existing monitoring apparatus, which comprises a preexisting beat detector. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the T wave filter separable from a preexisting beat detector in order to facilitate the upgradeability of a existing system, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Newin V. Erlincnman*, 168 USPQ 177, 179.

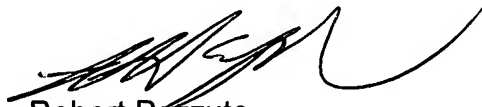
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason E. Rosenzweig whose telephone number is (571)272-5559. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason Rosenzweig
Patent Examiner
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